VII. 510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92, the following summary of information is provided:

A. Submitted by:

Ms. Han Fan
Regulatory Affairs Associate
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-3338
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B. Device Name

Trade or Proprietary Name:	*NuVasive Adjustable Vertebral Body Replacement System*
Common or Usual Name:	Spinal Intervertebral Body Fixation Orthosis
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Device Class:	Class II
Classification:	§888.3060
Product Code:	MQP

C. Predicate Devices

The subject *Adjustable Vertebral Body Replacement System* is substantially equivalent to the *NuVasive Mesh System* currently distributed commercially in the U.S. by NuVasive.

D. Device Description

The *NuVasive Adjustable VBR System* includes different sized adjustable height core and endplates to suit the individual pathology and anatomical conditions of the patient. The cores can extend in height to properly match the anatomy and the endplates come in three major types: symmetric, asymmetric, and round.

E. Intended Use

The *NuVasive Adjustable VBR System* is a vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues. The *NuVasive Adjustable VBR System* is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

F. Comparison to Predicate Devices

The subject device has indications for use identical to those of its predicate, and employs the same principles of operation.

G. Summary of Non-Clinical Tests

Mechanical testing was presented.

H. Summary of Clinical Tests

(Not Applicable).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nuvasive, Inc.
% Han Fan
7475 Lusk Boulevard
San Diego, California 92121

APR 2 7 2009

Re: K090176
Trade/Device Name: Adjustable Vertebral Body Replacement System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: April 9, 2009
Received: April 10, 2009

Dear Ms. Fan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative,
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K090176

Device Name: Adjustable VBR System

Indications For Use:

The *NuVasive Adjustable VBR System* is a vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues. The *NuVasive Adjustable VBR System* is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090176

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)